

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE AMITIZA ANTITRUST
LITIGATION

Master Docket No. 1:21-cv-11057-MJJ

REDACTED

THIS DOCUMENT RELATES TO

End-Payor Class Action

Civil Action No. 1:23-cv-12918-MJJ

**END-PAYOR PLAINTIFFS' OPPOSITION TO TAKEDA'S
MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF
EXPERT MARTIN E. KOVACH, Ph.D.**

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INTRODUCTION

Takeda¹ has already moved the Court to exclude opinions of eleven of the twelve experts submitted by the various plaintiff groups in this litigation. True to form, Takeda now seeks to exclude the testimony of Premera’s economics and data expert Martin E. Kovach, Ph.D. Specifically, Takeda asks the Court to preclude Dr. Kovach from testifying that: (1) third-party payors (“TPPs”) possess or can obtain claims data that, when presented, can confirm class membership in an administratively feasible manner—a conclusion reached by multiple courts that find TPP class actions ascertainable—and (2) all or virtually all TPPs were injured by Takeda’s anticompetitive actions to delay generic competition for its brand drug Amitiza—also a conclusion that is consistent with the multiple courts in similar “pay-for-delay” cases.²

Qualifications. Takeda manufactures a challenge to Dr. Kovach’s qualifications by ignoring his credentials. In spite of Dr. Kovach’s educational background in economics and 20 years working as an economist, Takeda proclaims that he is “not an economist.”³ Without explanation, Takeda dismisses Dr. Kovach’s “purported experience” drafting expert reports in pharmaceutical antitrust class actions,⁴ and neglects to even mention his co-authorship of a book on pharmaceutical data litigation—a book cited by other courts as evidence of his co-author’s expert qualification.

Ascertainability. Takeda claims Dr. Kovach’s opinions should be excluded because he personally “did not design a methodology to ascertain the class, Plaintiffs did.”⁵ But Neither F.R.E.

¹ Defendants Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals U.S.A., Inc., and Takeda Pharmaceuticals America, Inc. are referred to collectively as “Takeda.”

² See End-Payor Plaintiffs’ Memorandum of Law in Support of Second Amended Motion for Class Certification (“Cert. Br.”), Doc No. 396 § IV.D.

³ Takeda’s Memorandum of Law in Support of its Motion to Exclude Certain Opinions of Martin E. Kovach (“Kovach *Daubert*”), Doc No. 546 at 17.

⁴ *Id.* at 16.

⁵ *Id.* at 8; see also Takeda’s Sur-Reply in Opposition to End Payor Plaintiffs’ Motion for Class Certification (“Cert. Sur-Reply”), Doc No. 548 at 2 (incorrectly arguing that Dr. Kovach does “not help” because “he testified that he was not asked to devise a methodology for ascertaining members of the proposed classes”).

702, FED. R. CIV. P. 23, nor any other legal source require him to do so. To the contrary, class counsel's expert "***is not required*** to put forth a methodology for ascertainability, which is EPPs' burden to prove."⁶

Dr. Kovach provides reliable, relevant, and helpful expert testimony that supports multiple aspects of plaintiffs' proposed methodology of identifying class members by reference to TPPs' claims data and other sources.⁷ Dr. Kovach has good grounds for his testimony, which is rooted in his extensive experience analyzing claims data for litigation, and thorough review of claims data produced in this action, and Messrs. Fischer and Miller's declarations and testimony. Dr. Kovach does not "simply accept[]" anyone's "unsupported representations" nor make untethered references to his experience as Takeda claims.⁸

At its core, Takeda's motion is a mere carbon copy of the rejected *Daubert* motion its same counsel filed recently in *In re Generic Pharmaceuticals Pricing Antitrust Litig.*, in reliance on the same expert (Dr. Happe).⁹ As here, the *Generics* plaintiffs argued that a process wherein TPPs present their own data was tried and true. Also as here, *Generics* defendants argued that plaintiffs had not put forth a methodology.¹⁰ Again as here, defense counsel argued that Plaintiffs' expert had "not

⁶ *In re Generic Pharms. Pricing Antitrust Litig.*, No. 16-md-2724, 2024 WL 4980784, at *25 (E.D. Pa. Dec. 3, 2024) ("*Generics Daubert*") (emphasis added).

⁷ See *Generics Daubert*, 2024 WL 4980784, at *26 (holding plaintiffs' expert "provides good grounds to support the reliability of her opinions from which EPPs may draw to demonstrate ascertainability at class certification."); *In re Solodyn (Minocycline Hydrochloride Antitrust Litig.*, No. 14-md-02503, 2018 WL 734655, at *1 (D. Mass. Feb. 6, 2018) ("*Solodyn IP*") ("[T]he ascertainability requirement demands an 'objective criterion' upon which to define the class a standard ***the EPP class readily met*** with the ***support of [expert] DeBree's testimony***.")) (emphasis added).

⁸ Kovach *Daubert*, Doc No. 546 at 8.

⁹ See Defendants' Memorandum of Law in Support of Their Motion to Exclude the Opinions and Proposed Testimony of Laura R. Craft, *In re Generics Pharms. Pricing Antitrust Litig.* (E.D. Pa. Feb. 22, 2024), ECF No. 261; *Generics Daubert*, 2024 WL 4980784, at *30 ("Defendants instructed Dr. Happe "to assess and evaluate the approaches proposed by Plaintiffs to identify members of the proposed classes and eligible transactions" including the reports and opinions of EPPs' experts Ms. Craft and Mr. Miller.").

¹⁰ Compare Kovach *Daubert*, ECF No. 546, Expert Report of Laura E. Happe, Pharm.D., M.P.H. ("Happe Rep.") Doc No. 505-2 § V, and Takeda's Opposition to End Payor Plaintiffs' Motion for Class Certification ("Cert. Opp."), Doc No. 505 at 8-11 (arguing no methodology), with *Generics Daubert*, 2024 WL 4980784, at *24 (arguing no methodology).

offered a list or method by which class members could be systematically identified . . . [but] only implies the existence of reliable information, [] not an administratively feasible methodology in which to utilize that data to identify class members.”¹¹ The *Generics* court—even under the “heightened ascertainability” standard in the “outlier” Third Circuit¹²—properly rejected these arguments.¹³ They should be rejected here as well.

Classwide Antitrust Impact. Takeda offers no more than an *ipse dixit* assertion that Dr. Kovach lacked an empirical methodology to justify his conclusion that all or virtually all class members were injured by the alleged misconduct. Not true. Below, EPPs accordingly outline for the Court the publications and forecasts analyzed in Dr. Kovach’s reports and the widely accepted yardstick methodology he employed to calculate the vanishingly small probability that any class member TPP was uninjured by Takeda’s restraint of the market for Amitiza and generic Amitiza.

Takeda’s motion to exclude Dr. Kovach’s testimony should be denied.

FACTUAL BACKGROUND

A. Background

This case concerns Takeda’s alleged collusion with Sucampo Pharmaceuticals, Inc. (“Sucampo”) and Par Pharmaceutical, Inc. (“Par”) to unlawfully delay market entry of generic

¹¹ *Generics Daubert*, 2024 WL 4980784, at *25.

¹² *Gov. Emps. Health Ass’n v. Actelion Pharm. Ltd.*, No. GLR-18-3560, 2024 WL 4122123, at *12 (D. Md. Sept. 6, 2024) (“*Tracleer*”).

¹³ See *In re Generic Pharms. Pricing Antitrust Litig.*, No. 16-md-2724, 2025 WL 754567, at *21-25 (E.D. Pa. Mar. 7, 2025) (“*Generics Class Cert.*”) (finding damages class ascertainable because use of “claims data and affidavits provided by the end-payers themselves” was an administratively feasible method for determining whether putative class members fall within the class definition). Takeda includes a footnote—untethered to the rest of its motion—to assert that any use of affidavits is precluded by a Seventh Amendment right (i.e., at trial) to “to test the reliability of evidence submitted to prove class membership” at trial. Kovach *Daubert*, Doc No. 546 at 1 (citing *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013)); see also Cert. Sur-Reply, Doc No. 548 at 8-11. Takeda is wrong even under the Third Circuit’s heightened ascertainability standard, because “where plaintiffs possess records or other reliable means to determine class membership, the Third Circuit has held that they may also use affidavits to support ascertainability.” *Generics Class Cert.*, 2025 WL 754567, at *25 (citing *City Select Auto Sales, Inc. v. BMW Bank of N. Am, Inc.*, 867 F.3d 434, 441-42 (3d Cir. 2017)).

competition for the constipation drug Amitiza (lubiprostone). Plaintiffs allege that Takeda, along with its Amitiza commercialization partner Sucampo and generic manufacturer Par, executed a 2014 settlement agreement wherein Par agreed to delay launching its generic lubiprostone product until January 1, 2021—several years after its likely market launch—in exchange for Takeda and Sucampo’s commitment not to launch an authorized generic to compete with Par’s product during its period of generic exclusivity.¹⁴ Following discovery, EPPs moved for class certification of damages class and an unjust enrichment class. EPPs demonstrated that they meet each of the requirements of Rule 23 as well as the implied ascertainability requirement.¹⁵ In opposition, Takeda only disputed whether the proposed classes were ascertainable, and whether they met the predominance and superiority elements of Rule 23(b)(3).¹⁶

As EPPs explained in their class certification briefs, ascertainability requires that proposed class members be identifiable by objective criteria and in an administratively feasible manner.¹⁷ Contrary to Takeda assertions,¹⁸ ascertainability *does not* “require[] that a class be identified or even that the methodology for doing so be in place by the time of certification.”¹⁹ Rather, a “plaintiff need only show that ‘class members can be identified.’”²⁰ And that is precisely what EPPs did here—EPPs proposed a reliable and tested methodology and Dr. Kovach’s opinions supported it.

¹⁴ See Complaint, *Premiera Blue Cross v. Takeda Pharmaceutical Company, Ltd., et al.*, 1:23-cv-12918, Doc No. 1 ¶¶ 1-7, 107-62 (D. Mass. Nov. 30, 2023); see also *In re Amitiza Antitrust Litig.*, No. 21-11057-RGS, 2022 WL 17968695, at *2 (D. Mass. Dec. 27, 2022) (denying motion to dismiss the direct purchaser (“DPP”) action); 2024 WL 4344887, at *3 (D. Mass. Sept. 30, 2024) (adopting same holding for purpose of EPP claims).

¹⁵ See Doc Nos. 395-397.

¹⁶ Takeda’s Opposition to End Payor Plaintiffs’ Motion for Class Certification (“Cert. Opp.”), Doc No. 505.

¹⁷ Cert. Br., Doc No. 396 at 18; End-Payor Class Reply Memorandum of Law in Support of Motion for Class Certification (“Cert. Reply”), Doc No. 527 at 13-15, 18-19.

¹⁸ Cert. Br., Doc No. 505 at 10.

¹⁹ *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294, 308 (D. Mass. 2021) (citing *Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527, 549 (S.D.N.Y. 2021)).

²⁰ *In re HIV Antitrust Litig.*, No. 19-CV-02573-EMC, 2022 WL 22609107, at *35 (N.D. Cal. Sept. 27, 2022) (“[Ascertainability] does not mean that a plaintiff must be able to identify all class members at class certification – instead, a plaintiff need only show that ‘class members can be identified.’” (citation omitted)).

B. The Parties' Class Certification Experts

Dr. Kovach's Expert Opinions:

In his opening report, Dr. Kovach opined that: members of class were economically injured and that classwide damages were calculable using common evidence.²¹ In addition, in support of EPPs' ascertainability methodology, Dr. Kovach (1) evaluated TPP claims data and opined on whether it contains information sufficient to establish class eligibility, and (2) reviewed and opined on the contents of declarations concerning TPP claims data, submitted by Premera (Joey Coates), Mark Fischer, and Eric Miller.²²

Dr. Kovach opined that the claims data he reviewed was sufficient to determine, for each drug claim, the information relevant for determining class membership.²³ Dr. Kovach further drew from his twenty years of experience reviewing TPP claims data—and co-authoring a book about it—to conclude that the opinions of Mr. Fischer, President of Rawlings Analytics, LLC, an industry leading data analytics firm for the insurance industry that has access to claims data on over 300 million Americans, and Mr. Miller, Senior Vice President of Case Management at A.B. Data, Ltd.'s Class Action Administration Company—which has administered dozens of class settlements, including over forty certified TPP class settlements—were consistent with his experience.²⁴ Generally, Mr. Fischer testified that Rawlings can identify TPPs using claims data (and qualifying purchases) and has done so in submitting TPP claims in numerous TPP class action settlements.²⁵

²¹ Expert Report of Martin Kovach, Ph.D. in Support of Class Certification and the Calculation of Damages for the Class of End Payors ("Kovach Rep."), Doc No. 397-1, ¶¶ 4(a)-(e).

²² *Id.* ¶ 18.

²³ *Id.* ¶¶ 4(f), 127-33; *see* Cert. Br., Doc No. 396 at 18-20.

²⁴ Kovach Rep., Doc No. 397-1, ¶¶ 128-130; *see also* Declaration of Eric J. Miller ("Miller Decl."), Doc No. 397-9, ¶¶ 1, 3-5, & Ex. A at 8-15 (listing cases); Deposition Transcript of Eric Miller ("Miller Dep. Tr."), Doc No. 547-3 at 212:11-213:23; Declaration of Mark D. Fischer ("Fischer Decl."), Doc No. 397-8, ¶¶ 1-8.

²⁵ Kovach Rep., Doc No. 397-1, ¶¶ 128-30; *see also* Fischer Decl., Doc No. 397-8, ¶ 9-12. As elaborated upon in his deposition, Mr. Fischer explained that Rawlings is routinely retained to use claims data to answer complex litigation

And Mr. Miller testified both that confirming class membership using TPP data was

██████████ and that TPPs regularly obtain and submit their data.²⁶ Ms. Coats, Premera's Director of Pharmacy and Clinical Consulting, testified that Premera (a TPP and insurer) maintains data with information necessary to determine class membership, and that the data distinguishes its self-funded and fully insured lines of business ██████████²⁷

After Takeda's expert, Dr. Happe, attacked the administrative feasibility of obtaining and using TPP data to confirm class membership, Dr. Kovach responded to and rebutted her critiques.²⁸ In response to Dr. Happe's opinions that obtaining TPP data was not ██████████ Dr. Kovach noted TPPs regularly present their claims data themselves, such as in the claims administration processes run by A.B. Data.²⁹ In response to Dr. Happe's opinion that obtaining data from Rawlings was also not feasible, Dr. Kovach explained that Rawlings already has access to claims data from 300 million Americans, and additional subpoenas could be used to collect whatever insurer data was needed beyond that (as the top 100 insurers cover ~97% of pharmaceutical claims in the U.S.).³⁰ In response to Dr. Happe's critique that applying exclusions would not be feasible, Dr. Kovach explained that TPPs know their funding status and can present their data in conforming structures, as they regularly do, and, that information on excluded government entities was publicly available.³¹

Dr. Happe's Expert Opinions:

questions, such as identification of damages by TPPs for spend on opioids-related products caused by opioid use disorder. Deposition Transcript of Mark Fischer ("Fischer Dep. Tr."), Doc No. 547-2 at 47:14-19, 150:9-17.

²⁶ Kovach Rep., Doc No. 397-1, ¶¶ 129-30; *see also* Miller Decl., Doc No. 397-9, ¶¶ 20-33; *Generics Class Cert.*, 2025 WL 754567, at *23, *25 (crediting the same testimony from Mr. Miller while finding his opinions "reliable").

²⁷ Kovach Rep., Doc No. 397-1 ¶¶ 131-32; *see also* Premera Decl., Doc No. 397-10 ¶¶ 6-11.

²⁸ Reply Expert Report of Martin Kovach, Ph.D. in Support of Class Certification and the Calculation of Damages for the Class of End Payors ("Kovach Rbl."), Doc No. 528-1, ¶¶ 114-63.

²⁹ *Compare* Expert Report of Laura E. Happe, Pharm.D., M.P.H. ("Happe Rep."), Doc No. 505-2, ¶¶ 47-48, *with* Kovach Rbl., Doc No. 528-1, ¶¶ 120-21.

³⁰ *Compare* Happe Rep., Doc No. 505-2, ¶¶ 49-51, *with* Kovach Rbl., Doc No. 528-1, ¶¶ 123-24, 134-36.

³¹ *Compare* Happe Rep., Doc No. 505-2, ¶¶ 49-51, *with* Kovach Rbl., Doc No. 528-1, ¶¶ 153-63.

Dr. Happe generally opined that [REDACTED]

[REDACTED]³² Not only did Judge Rufe reject this same basic premise in *Generics* (where she was also partially excluded Dr. Happe as an expert),³³ at her deposition in this case, Dr. Happe *agreed* to many of the same conclusions Dr. Kovach reached. For example:

- TPPs have or can obtain claims data³⁴ which Dr. Happe characterized as [REDACTED]³⁵ and which show: (1) date (2), the drug purchased, (3) price, (4) quantity, (5) patient state of residence, and (6) an identifier of who paid the pharmacy.³⁶
- [REDACTED]³⁷ (The *Generics* court relied on this same concession in finding the TPP damages class ascertainable).³⁸
- [REDACTED]³⁹
- Insurers know which of their customers are state or federal entities.⁴⁰
- TPPs possess objective documentary evidence that establishes if they are a government entity or are the insurer agent of a government entity.⁴¹

³² Happe Rep., Doc No. 505-2, ¶¶ 16, 17.

³³ Compare *id.* ¶¶ 16-17, with *Generics Daubert*, 2025 WL 4980784, at *24-26 (rejecting argument that TPPs presenting their data with certifications was neither a methodology nor administratively feasible); *id.* at *30-31 (excluding Dr. Happe's opinions on the notice process as "impermissibly speculative" and finding "Dr. Happe is not qualified to opine on the class notice process"); see also *Generics Class Cert.*, WL 754567, at *21-26 (rejecting arguments raised on *Daubert*, and that a process using TPP data "improperly relies on the claims administration process").

³⁴ Declaration of Charles Kopel, April 30, 2025, Ex. D Deposition Transcript of Laura Happe ("Happe Dep. Tr."), Doc No. ___ at 153:11-16 (confirming that TPPs [REDACTED]).

³⁵ Happe Rep., Doc No. 505-2, ¶ 44 (emphasis added).

³⁶ Happe Dep. Tr., Doc No. ___ at 90:22-93:9 [REDACTED], 146:1-12 [REDACTED], 200:6-14 [REDACTED].

³⁷ *Id.* at 57:4-5.

³⁸ *Generics Class Cert.*, 2025 WL 754567, at *24 ("Dr. Happe opined that insurers are always able to differentiate between fully insured and self-funded plans.").

³⁹ Happe Dep. Tr., Doc No. ___ at 112:3-6.

⁴⁰ *Id.* at 141:24-142:3 [REDACTED]

⁴¹ Happe Dep. Tr., Doc No. ___ at 138:3-4 [REDACTED]. Dr. Happe also confirmed that [REDACTED] Happe Rep., Doc No. 505-2, ¶ 45.

- Amitiza claims data is no different than claims for the drugs other certified TPP classes.⁴²

LEGAL STANDARD

“Federal Rule of Evidence 702 ‘assign[s] to the trial judge the task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.’”⁴³ “The ultimate purpose of the *Daubert* inquiry is to determine whether the testimony of the expert would be helpful to the jury in resolving a fact in issue.”⁴⁴ Though courts act as a “gatekeeper” in this regard, they “must . . . keep in mind the Supreme Court’s admonition that ‘[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.’”⁴⁵ “The soundness of the factual underpinnings of the expert’s analysis and the correctness of the expert’s conclusions based on that analysis are factual matters to be determined by the trier of fact.”⁴⁶ As such, “[i]f an expert’s testimony is within ‘the range where experts might reasonably differ,’ the jury, not the trial court, should be the one to ‘decide among the conflicting views of different experts.’ ‘Only if the expert’s opinion is so fundamentally unsupported that it can offer no assistance to the jury must such testimony be excluded.’”⁴⁷

“*Daubert* does not require that a party who proffers expert testimony carry the burden of

⁴² *Id.* at 162:25-163:3.

⁴³ *Cipollone v. Yale Indus. Products, Inc.*, 202 F.3d 376, 380 (1st Cir. 2000) (alteration in original) (quoting *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 597 (1993)).

⁴⁴ *Id.*

⁴⁵ *In re Neurontin Mktg. Sales Practices, and Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 131 (D. Mass. 2009) (alteration in original, internal citations omitted).

⁴⁶ *Milward v. Acuity Specialty Prod. Grp, Inc.*, 639 F.3d 11 at 22 (1st Cir. 2011) (citation omitted); *United States v. Vargas*, 471 F.3d 255, 264 (1st Cir. 2006) (“When the factual underpinning of an expert’s opinion is weak, it is a matter affecting the weight and credibility of the testimony—a question to be resolved by the jury.”) (citation omitted).

⁴⁷ *In re Neurontin Mktg. Sales Practices, and Prods. Liab. Litig.*, 612 F. Supp. 2d 116, 131 (D. Mass. 2009) (internal citations omitted); see also *In re Solodyn Antitrust Litig.*, No. 14md2503, 2018 WL 563144, at *2 (D. Mass. Jan. 25, 2018) (quoting *Daubert*, 509 U.S. at 596).

proving to the judge that the expert’s assessment of the situation is correct.”⁴⁸ Rather, “[a]s long as an expert’s scientific testimony rests upon ‘good grounds, based on what is known,’ it should be tested by the adversary process—competing expert testimony and active cross-examination—rather than excluded from jurors’ scrutiny for fear that they will not grasp its complexities or satisfactorily weigh its inadequacies.”⁴⁹

ARGUMENT

I. Dr. Kovach is Qualified to Offer All of His Expert Opinions as he has Extensive Training and Experience on the Issues on which he Opines.

Takeda challenges Dr. Kovach’s qualifications to provide expert testimony on (a) “class member ascertainability” and (b) “economic analysis.”⁵⁰ These broadside challenges fail for the simple reason that Dr. Kovach possesses standard criteria for expert admissibility. He earned a Ph.D. in Environmental Studies from the University of California, Santa Cruz, concentrating on “the intersection of environmental economics and environmental policy.”⁵¹ To earn that degree, Dr. Kovach completed extensive economics coursework.⁵² He has also worked for **20 years** as an economist at a litigation consultant firm, specializing in pharmaceutical antitrust litigation.⁵³ In these pharmaceutical cases, Dr. Kovach serves as a project manager, performing economic analysis involving claims data, calculating damages, and producing drafts of class certification expert reports.⁵⁴ Dr. Kovach has also provided expert testimony before, serving as the damages expert on behalf of three Indian tribe plaintiffs in *In Re: JUUL Labs, Inc., Marketing, Sales Practices, and Products*

⁴⁸ *Ruiz-Troche v. Pepsi Cola of Puerto Rico Bottling Co.*, 161 F.3d 77, 85 (1st Cir. 1998) (citing *Daubert*, 509 U.S. at 590).

⁴⁹ *Id.* (internal citations omitted).

⁵⁰ Kovach *Daubert*, Doc No. 546 at 9, 17. This comprehensive assault undermines Takeda’s characterization of its *Daubert* motion as only targeting “certain” of Dr. Kovach’s opinions. *See id.* at 1, 2.

⁵¹ Kovach Rep., Doc No. 397-1, ¶ 9.

⁵² Kovach Dep. Tr., Doc No. 547-1 at 13:17-23.

⁵³ *Id.* at 11:20-24. Rule 702(a) allows experts to rely upon this type of “specialized knowledge.” F.R.E. 702(a).

⁵⁴ *Id.* at 210:6-211:1.

Liability Litigation, Case No. 19-md-02913-WHO (N.D. Cal.). Drawing upon this professional experience, in 2017, Dr. Kovach co-authored a book on the use of pharmaceutical data in litigation.⁵⁵ These factors—“education,” “work experience,” and “publication in the pertinent field”—are all regularly regarded as indicia of expert qualification under *Daubert*.⁵⁶

Takeda sidesteps the nature of Dr. Kovach’s degree concentration and coursework in its motion, and asserts that he “is not an economist,” not a “healthcare economist,” and does not hold any degrees in economics.⁵⁷ Even if this were a reasonable characterization—it is not—holding a formal economics degree **is not** a necessary condition for qualification as an economist.⁵⁸ Similarly, Takeda’s challenge to the value of Dr. Kovach’s experience as a litigation consultant is contrary to caselaw and F.R.E. 702(a) itself.⁵⁹ And the fact that Dr. Kovach has not been previously “qualified as an economist,”⁶⁰ is also not grounds for disqualification.⁶¹

Takeda’s qualification arguments split hairs, arguing, for instance, that Dr. Kovach’s experience with pharmaceutical pricing class action litigation does not extend to ascertainability,

⁵⁵ See EMPIRICAL CHALLENGES IN PHARMA LITIGATION (OnPoint Analytics, Inc., 2017). Two courts have cited Laura Craft’s co-authorship of this book, with Dr. Kovach, in support of their decisions to find her qualified as an expert witness with respect to ascertainability. See *Tracleer*, 2024 WL 4122123, at *7; *In re Loestrin 24 FE Antitrust Litig.*, 410 F.Supp.3d 352, 386 (D.R.I. 2019).

⁵⁶ *Grayson v. No Labels, Inc.*, 599 F. Supp. 3d 1184, 1189 (M.D. Fla. 2022).

⁵⁷ Kovach *Daubert*, Doc No. 546 at 17.

⁵⁸ See, e.g., *MicroVention, Inc. v. Balt USA, LLC*, No. 8:19-cv-01335-JLS-KES, 2022 WL 4596647, at *6 (C.D. Cal. Aug. 24, 2022) (rejecting argument that expert “may not testify that he is an economist as he does not have a degree in economics”); *In re Se. Milk Antitrust Litig.*, No. 2:08-MD-1000, 2010 WL 11462847, at *3 (E.D. Tenn. Dec. 9, 2010) (“[T]o again address Mr. Elhauge’s qualifications to testify on antitrust economics, the fact that he holds no degree in economics does not disqualify him. He can show that he is qualified by experience.”).

⁵⁹ See, e.g., *Mullinex v. John Crane, Inc.*, No. 4:18-cv-33, 2020 WL 1316657, at *2 (E.D. Va. Feb. 6, 2020) (qualifying expert who “bec[a]me familiar with [the subject matter] over the past fifteen years as a litigation consultant”); *Willis v. Big Lots, Inc.*, No. 2:12-cv-604, 2017 WL 1074048, at *2-3 (S.D. Ohio Mar. 17, 2017) (qualifying economic expert without an economics degree or academic affiliation on the basis of his experience “conduct[ing] various financial and economic analyses” for litigation consulting firms).

⁶⁰ Kovach *Daubert*, Doc No. 456 at 17.

⁶¹ See *Zambrano v. Sparkplug Capital, LLC*, No. 19 CV 100, 2022 WL 2657224, at *2 (N.D. Ill. July 8, 2022) (“[T]here is a first time in court for every expert”); *United States v. Williams*, No. CR-18-01695-TUC-JAS (EJM), 2023 WL 334290, at *25 (D. Ariz. Jan. 20, 2023) (noting that a requirement of previous expert testimony constitutes a “circular argument” and “would mean that there would never be expert testimony”).

despite acknowledging his testimony that he assisted in an expert report on ascertainability in the *Restasis* litigation.⁶² It emphasizes also that Dr. Kovach's *Restasis* work involved PBM and pharmacy data rather than insurer claims data, ignoring his testimony that "I've worked with claims data for nearly 20 years."⁶³ Takeda's feeble attempts to thinly compartmentalize areas of expertise contravene the overwhelming weight of *Daubert* caselaw and, therefore, must fail.⁶⁴

II. Dr. Kovach's Opinions Supporting EPPs' Methodology for Identifying Class Members are Reliable and Relevant to Ascertainability.

A. Dr. Kovach's Opinions Regarding the Availability and Capabilities of Data Provide Strong Evidentiary Support for Plaintiffs' Proposed Process for Confirming Class Membership.

Takeda's claim that Dr. Kovach does not know "what methods plaintiffs are proposing," improperly jumbles the roles of the litigant (EPPs) and the expert (Dr. Kovach) with regard to ascertainability.⁶⁵ EPPs proposed a methodology to identify class members in an administrable feasible manner, and Dr. Kovach added support to that by providing expert opinions on certain aspects (*e.g.*, the sufficiency of TPP claims data; whether TPP claims data informs funding status).⁶⁶ Dr. Kovach did not and need not independently propose an ascertainability methodology of his own for his opinions to be reliable and relevant.⁶⁷

⁶² Kovach *Daubert*, Doc No. 546 at 16 (citing Kovach Dep. Tr., Doc No. 547-1 at 82:7-84:14).

⁶³ Kovach Dep. Tr., Doc No. 547-1 at 54:5-6. Dr. Kovach also clarified how this experience with claims data is precisely what qualifies him to opine on an ascertainability methodology. *See id.* at 44:25-45:5 ("I have used these datasets extensively...enough to -- to understand that they can be used for [ascertaining class membership].").

⁶⁴ *See Microfinancial, Inc. v. Premier Holidays Int'l, Inc.*, 385 F.3d 72, 80 (1st Cir. 2004) ("When, as in this case, an expert is qualified . . . by knowledge, skill, experience, training, or education, he need not have had first-hand dealings with the precise type of event that is at issue.") (citations and quotations omitted).

⁶⁵ Kovach *Daubert*, Doc No. 546 at 9-10.

⁶⁶ *See* Kovach Rep., Doc No. 397-1, ¶¶ 127-33; Kovach Rbl., Doc No. 528-1 ¶¶ 116-127.

⁶⁷ *See Generics Daubert*, 2024 WL 4980784, at *25-26 (class counsel's expert "is not required to put forth a methodology for ascertainability, which is EPPs' burden to prove"; "plaintiffs' expert "provides good grounds to support the reliability of her opinions from which EPPs may draw to demonstrate ascertainability at class certification."); *Solodyn II*, 2018 WL 734655, at *1 ("[T]he ascertainability requirement demands an 'objective criterion' upon which to define the class, a standard *the EPP class readily met*, with the *support of [expert] DeBree's testimony*." (emphasis added)).

Takeda also ignores Dr. Kovach's repeated explanation at his deposition of what aspects of EPPs' methodology he opines on.⁶⁸

B. Dr. Kovach has “Good Grounds” for his Opinions Concerning the Source and Content of Data Relied Upon by Plaintiffs.

Dr. Kovach bases his opinions supporting Plaintiffs' methodology of identifying class members by reference to TPPs' claims data and other sources on his (1) extensive experience analyzing claims data for litigation; (2) thorough review of claims data produced in this case; as well as (3) his review of declarations and testimony in this case.⁶⁹ He did not “blindly rely” on witnesses' representations as Takeda insists.⁷⁰ Rather, he couples this information with “his own analysis to form his opinion,” which is perfectly permissible.⁷¹ Thus, Dr. Kovach has “good grounds” for his opinions “based on what is known,”⁷² and Takeda is mistaken in suggesting otherwise.

First, Dr. Kovach is not opining on the “substance or availability of Rawlings data.”⁷³ Dr. Kovach concludes that Mr. Fischer's declaration regarding Rawlings data is *consistent with* his “knowledge of prescription drug claims data,” the claims data he reviewed in this case; and his “own experience working with this data.”⁷⁴

⁶⁸ See e.g., Kovach Dep. Tr., Doc No. 547-1 at 25:6-15, 26:1-6 (claims data available to TPPs and insurers can be used to ascertain class); *id.* at 124:17-125:14, 125:24-126:1, 126:17-19 (methods are available to apply class definition exclusions); *id.* at 143:24-145:24, 158:13-161:2 (insurers' purchases on behalf of fully insured entities, private or governmental, should not be excluded); *id.* at 97:11-17, 99:10-12, 123:2-124:1 (methods for using different datasets).

⁶⁹ See Kovach Rep., Doc No. 397-1, ¶¶ 127-33; Kovach Rbl., Doc No. 505-3, ¶¶ 114-63.

⁷⁰ Kovach *Daubert*, Doc No. 546, at 15.

⁷¹ See *Cashman Dredging & Marine Contracting Co., LLC v. Belesimo*, No. 21-cv-11398-DJC, 2024 WL 4894639, at *18 (D. Mass. Nov. 26, 2024) (noting that “an expert may rely on other witness's testimony or other conclusions to form an opinion,” and excluding expert who - unlike Dr. Kovach - failed to “conduct his own analysis to form his opinion”); *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, No. 20-md-02966-RS, 2024 WL 4023562, at *10 (N.D. Cal. Aug. 26, 2024) (denying *Daubert* of expert who is “properly relying upon and incorporating other expert opinions into his analysis.”).

⁷² *Daubert*, 509 U.S. at 590.

⁷³ Kovach *Daubert*, Doc No. 546 at 11.

⁷⁴ Kovach Rep., Doc No. 397-1, ¶¶ 130-32; Kovach Rbl., Doc No. 505-3, ¶ 134; Kovach Dep. Tr., Doc No. 547-1 at 54:1-11 (Mr. Fischer's declaration “is consistent with my own experience of claims data. . . . I've worked with

As to the Rawlings data itself, Mr. Fischer testifies that Rawlings has access to claims data for over 300 million Americans; can generate reports for claims data based on drug product, and has successfully identified multiple claims for its TPP clients to file in certified TPP antitrust class settlements.⁷⁵ Mr. Fischer further testified that Rawlings archives its data and can retrieve it if necessary.⁷⁶ Based on his assessment of Mr. Fischer's sworn statement and testimony, and specifically that Rawlings has data for over 300 million Americans, Dr. Kovach conducted an independent analysis to conclude that "Rawlings has access to data for a large majority of covered lives in the United States," and that data containing the information sworn to by Mr. Fischer could be used to ascertain the class in an administratively feasible manner.⁷⁷ Takeda's insinuates that while Rawlings' data includes all other prescription drugs, it is possible that it may not include Amitiza.⁷⁸ Just restating the argument emphasizes its implausibility. Moreover, with regard to using TPP data to identify class members, as both EPPs and Dr. Kovach note, to the extent additional TPP data is needed, it can be subpoenaed from health insurance companies.⁷⁹

Second, Takeda argues that Dr. Kovach's "review of data in this case" fails to support his opinion that plan funding status (i.e., whether the plan is fully insured or self-funded) can be ascertained from TPPs' claims data.⁸⁰ This is false, and demonstrably so. As Dr. Kovach details in his Rebuttal Report, his review of the data showed that "[t]he funding status of plan sponsors can be

claims data for nearly 20 years."). *See also Generics Class Cert.*, 2025 WL 754567, at *24 (citing statements by Rawlings Analytics as support that "EPPs have sufficiently demonstrated that they can use the proposed data sets to ascertain membership in the class. EPPs are not required to identify every class member at this stage in the litigation, but only to show that there is a feasible method by which they can identify class members.").

⁷⁵ *See* Fischer Decl., Doc No. 397-8, ¶¶ 6, 8, 12; *Generics Class Cert.*, 2025 WL 754567, at *24 (noting that Rawlings Analytics "manages healthcare data covering over 300 million Americans.").

⁷⁶ Fischer Dep. Tr., Doc No. 547-2 at 76:8-16.

⁷⁷ Kovach Rbl., Doc No. 528-1, ¶¶ 122-27, ¶ 123 n. 198 (estimating number of insured people in the United States to be 314.8 million based on government and academic sources), ¶ 134-36.

⁷⁸ *See* Kovach *Daubert*, Doc No. 546 at 11.

⁷⁹ Cert. Reply, Doc No. 527 at 16-17; Kovach Rbl., Doc No. 528-1, ¶ 123.

⁸⁰ Kovach *Daubert*, Doc No. 546 at 12.

easily determined from the health insurers' claims data."⁸¹ In doing so, he refutes Dr. Happe and Dr. Strombom's arguments to the contrary and explains how data dictionaries provide a "simple solution" to addressing any ambiguities in the data.⁸² Indeed, Dr. Kovach's opinion is consistent with the *Generics* court, which highlighted that Takeda's expert Dr. Happe herself opined "insurers ***are always able to differentiate*** between fully insured and self-funded plans."⁸³

Takeda's criticism hinges on, first, undermining Dr. Kovach's opinion that "data dictionaries" can be used to resolve any ambiguities in funding type, because he did not review dictionaries for each of the datasets and, second, speculating that other datasets may not include information for funding type.⁸⁴ But this too is not in dispute, as Dr. Happe herself confirmed a data dictionary could be used to interpret ambiguous funding type values and that she would [REDACTED]
[REDACTED]"⁸⁵ Moreover, Dr. Kovach testified that he has worked in "many cases in which claims data was produced" and in any case in which a data dictionary was needed to interpret the data, the relevant entities "were easily able to generate that."⁸⁶ Dr. Kovach also supports his opinion that UnitedHealth has data concerning plan funding type even though it was missing from its initial production.⁸⁷ Indeed, here too, Dr. Happe testified [REDACTED].⁸⁸

⁸¹ Kovach Rbl., Doc No. 528-1, § IV.D.1.

⁸² *Id.* ¶ 146.

⁸³ *Generics Class Cert.*, 2025 WL 754567, at *24 (emphasis added).

⁸⁴ See Kovach *Daubert*, Doc No. 546 at 12.

⁸⁵ Happe Dep. Tr., Doc No. ___ at 88:6-14; Happe Rep., Doc No. 505-2, ¶ 61 fn. 98 ("[REDACTED]
[REDACTED] (emphasis added)).

⁸⁶ Kovach Dep. Tr., Doc No. 547-1 at 112:19-113:7; see Kovach Rbl., Doc No. 528-1, ¶¶ 144 ("When producing claims data, health insurers routinely produce a data dictionary along with it."), 149 ("[I]t is standard for a health insurer to produce a data dictionary with it[s] claims data.").

⁸⁷ See Kovach Rbl., Doc No. 528-1, ¶¶ 130, 140.

⁸⁸ Happe Dep. Tr., Doc No. 528-5 at 166:6-13.

Put simply, Dr. Kovach's analysis of the claims data produced in this case coupled with his extensive experience analyzing claims data supports his conclusion that available insurer claims data includes information concerning funding type.

Third, Takeda complains that Dr. Kovach fails to explain what standardizing claims data consists of and how it could be carried out.⁸⁹ That is incorrect. While Dr. Kovach has explained that Takeda's insistence that standardizing different insurer datasets *into one data set* is wholly unnecessary for ascertaining class members, he makes clear that standardization could easily be done, including by conforming the data "so that the field names match and the values in the fields match."⁹⁰ Likewise, if data fields contain different sets of codes, they "could be standardized across datasets."⁹¹ He further explains that this is "a simple programming task that I have personally undertaken and overseen in my nearly 20 years of experience working with prescription drug claims data for pharmaceutical litigation and could be done across all the claims datasets."⁹² Though "[a]n expert is permitted to testify on the basis of his experience,"⁹³ as the above makes clear, Dr. Kovach does not simply make a "[g]eneric appeal[]"⁹⁴ to his, nor does he merely "defer[]" to non-party declarants.⁹⁵ To the contrary, though he notes that A.B. Data combines TPP claims data—which

⁸⁹ Kovach *Daubert*, Doc No. 546, at 13.

⁹⁰ Kovach Rbl., Doc No. 528-1, ¶ 125.

⁹¹ *Id.*

⁹² *Id.*; see *id.* ¶¶ 144 ("[A]ddressing difference in field names is a simple and routine part of data analysis for litigation."), 145 ("In my experience, the different insurers maintain essentially the same data; only the field names within the data can at times diverge. Writing code to convert different health insurers' field names to a common set of field names is not an individualized analysis; it is a routine programming project applied to the aggregated claims dataset.").

⁹³ *Wyman v. Yates-American Machine Co.*, 13-cv-00300, 2016 WL 6441006, at *9 (D. Me. Oct. 31 2016) (citing *Brown v. Wal-Mart Stores, Inc.*, 402 F. Supp. 2d 303, 308 (1st Cir. 2005)).

⁹⁴ Kovach *Daubert*, Doc No. 546, at 13 (quoting *Earley Info. Sci. Inc. v. Omega Eng'g, Inc.*, 575 F. Supp. 3d 242, 248 (D. Mass. 2021)). Dr. Kovach's analysis is a far cry from the expert opinion excluded in *Earley*. There, the proposed expert based his conclusions on an approach "created solely for the purpose of this litigation" that he had never seen "utilized, discussed, or published in the relevant industry." *Earley Info. Sci. Inc.*, 575 F. Supp. 3d at 248.

⁹⁵ Kovach *Daubert*, Doc No. 546 at 13.

itself is proof that standardization of TPP claims data is not only doable, it has been done—he undertakes a separate analysis opining that TPP claims data can be standardized.

Takeda supposes that the standardization of claims data undertaken by A.B. Data is unique to the template format A.B. Data uses in its class action administration. But Dr. Kovach’s opinion regarding standardization is not contingent on data being provided in a specific template format.⁹⁶ Nor is it contingent upon TPP claims data being combined into a single set.⁹⁷ Moreover, for EPPs to identify class members here, Takeda fails to explain why they cannot, like A.B. Data, request that the data be provided in a format that would simplify standardization.

Fourth, Takeda ignores that “an expert may rely on another witness’s testimony or other expert conclusions to form an opinion” so long as he “conduct[s] his own analysis to form his opinion,” which its own authority implies.⁹⁸ This is precisely what Dr. Kovach does in opining that federal and state government entities can be excluded from claims data. As a starting point, based solely on his review of the claims data, Dr. Kovach opines that the “name of the plan sponsor . . . can be used in most cases to determine whether the plan sponsor is a federal or state government entity,” and information on the “type of plan” can be used to exclude Medicaid plans.⁹⁹

For the limited entities that may require clarification, Dr. Kovach combines his experience with information provided by Messrs. Fischer and Miller’s sworn testimony. For instance, Dr. Kovach testified that he has seen datasets including information about whether an entity was a federal or state government entity, which is the relevant information contained in the enrollment

⁹⁶ See Kovach Rbl., Doc No. 528-1, ¶ 125.

⁹⁷ See *id.* ¶ 126 (“If necessary, after the different claims datasets have been standardized, they could be combined.”)

⁹⁸ *Cashman Dredging & Marine Contracting Co., LLC*, 2024 WL 4894639, at *18 (cited by Takeda in Kovach *Daubert*, Doc No. 546 at 15 n. 93).

⁹⁹ Kovach Rbl., Doc No. 528-1, ¶ 119.f..

databases Mr. Fischer references.¹⁰⁰ Likewise, Dr. Kovach considered the relevant substance of potential TPP certifications of whether they are federal or state government entities, identified it during his deposition, and explained how it could be used to exclude federal and state government entities from claims data.¹⁰¹ As to health insurers' ability to identify federal and state government entities (and therefore omit it from its data or create a list of such entities) this issue is *not* in dispute: Dr. Happe conceded that [REDACTED].¹⁰² Indeed, other courts addressing ascertainability in similar "pay-for-delay" class actions have endorsed this approach to exclude federal and state government entities.¹⁰³

III. Dr. Kovach Employs an Accepted Quantitative Method to Demonstrate Classwide Antitrust Impact.

Takeda challenges the admissibility of Dr. Kovach's determination that "all or virtually all Class members were injured" by Takeda's preventing generic competition to Amitiza.¹⁰⁴ Takeda formulates this objection in several different ways, none of which are derived from *Daubert* caselaw, and none of which accurately describe Dr. Kovach's analysis. Takeda suggests that Dr. Kovach's classwide impact analysis is "not based on empirical evidence," "lacks any quantitative foundation," and/or "fails to calculate the numbers that would validate [Dr. Kovach's] conclusion."¹⁰⁵ In reality—a reality entirely disregarded by Takeda—Dr. Kovach's offers this antitrust impact

¹⁰⁰ See Kovach Dep. Tr., Doc No. 547-1 at 132:21-133:3; Kovach Rbl., Doc No. 528-1, ¶ 119.f (citing Fischer Dep. Tr., Doc No. 547-2 at 105:2-106:18, 156:6-20, 157:2-11).

¹⁰¹ Kovach Dep. Tr., Doc No. 547-1 at 140:9-19.

¹⁰² See Kovach Rbl., Doc No. 528-1, ¶ 162 (citing Happe Dep. Tr., Doc No. ___ at 204:18-22, 141:24-142:3).

¹⁰³ See, e.g., *Loestrin*, 410 F. Supp. 3d at 401 ("With respect to state and federal governmental entities, the EPPs will request that the PBMs remove federal and state plans from their dataset and, in addition, OnPoint will be able to identify them by name."); *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 18-md-2836, 2020 WL 5778756, at *11 (E.D. Va. Aug. 14, 2020). Takeda makes the proposition that Dr. Kovach "could not identify [publicly available sources] when asked," but it only cites to Dr. Kovach's testimony regarding enrollment data. Kovach *Daubert*, Doc No. 546 at 15 (citing Kovach Dep. Tr., Doc No. 457-1 at 134:6-135:18). Regardless, Dr. Kovach could, in fact, identify publicly available sources. Kovach Dep. Tr., Doc No. 457-1 at 136:1-137:13.

¹⁰⁴ Kovach *Daubert*, Doc No. 546 at 18 (quoting Kovach Rep., Doc No. 397-1, ¶ 58).

¹⁰⁵ Kovach *Daubert*, Doc No. 546 at 18-19.

conclusion “based on a reliable methodology and substantial evidence that he carefully explained.”¹⁰⁶

Dr. Kovach exhaustively outlines his empirical process. First, he examines a series of academic publications, government reports, and industry reports concluding that generic drugs enter the market at prices significantly lower than the reference brand drug, and that generic prices decline over time, as additional generic competitors enter.¹⁰⁷ Second, he assessed studies concluding that AB-rated generic drugs capture 80% to 90% of market share from the brand within 12 months.¹⁰⁸ Third, he drew upon record evidence to show that forecasts by Takeda itself and its generic competitors projected that the Amitiza market would follow the standard course of price decrease and market conversion following generic entry.¹⁰⁹ Fourth, he finds that the actual market followed the same course in the months following the (delayed) real-world launch of generic lubiprostone.¹¹⁰

Finding the assumptions of substantial price decrease and generic conversion well supported by these four forms independent categories of evidence, Dr. Kovach applied them to estimate the probability that any individual class member was injured. Assuming the well-documented generic conversion rate of 80% to 90%, a “simple probability analysis” shows the vanishing likelihood that any TPP would have continued to purchase higher-cost brand Amitiza in a but-for world with generic entry: “10% for a TPP with one Amitiza prescription, 1% for a TPP with two Amitiza prescriptions, and 0.1% for a TPP with three Amitiza prescriptions”¹¹¹ And as demonstrated above on the basis of academic literature, comparator case studies, and real-world generic lubiprostone data, each TPP’s purchase of a generic in the but-for world would have been at a substantial price

¹⁰⁶ See *Milward v. Acuity Specialty Prods. Grp., Inc.*, 639 F.3d 11, 22-23 (1st Cir. 2011).

¹⁰⁷ Kovach Rep., Doc No. 397-1, ¶¶ 59-66.

¹⁰⁸ *Id.* ¶ 67.

¹⁰⁹ *Id.* ¶¶ 68-73. See also Kovach Dep. Tr., Doc No. 547-1 at 171:9-172:2 (explaining that the 65 drug manufacturer forecasts Dr. Kovach considered included assessments of the sequence of generic market entry, the rate of generic conversion, and the movement of generic prices).

¹¹⁰ Kovach Rep., Doc No. 397-1, ¶¶ 74-78.

¹¹¹ *Id.* ¶ 82.

discount to brand Amitiza.¹¹² Further, any TPP with any generic lubiprostone purchases in the actual world would have made those same purchases in the but-for world at a lower price, because the entry of additional generics would have progressively decreased prices in the but-for world.¹¹³ Thus, Dr. Kovach concluded that “all or virtually all members of the Classes were injured by the alleged delay in generic entry.”¹¹⁴ In his Reply Report, Dr. Kovach refutes the criticisms Dr. Strombom lodges against his methodology¹¹⁵—none of which Takeda even mentions in its motion—and provides further empirical analysis to support his conclusion.¹¹⁶

Reading Takeda’s motion leaves one with the impression that it was not looking at the same Kovach Reports. The Kovach Reports utilize quantitative analysis and obtain quantitative results (*i.e.*, that, based on a probability analysis of IQVIA Xponent data, each Class member has only a 1%-2% probability of not paying for the generic in the but-for world).¹¹⁷ These quantitative results lead to an empirically supported conclusion that all or virtually all class members were injured. So, Takeda’s criticism that it is somehow “not clear” what Dr. Kovach means by “all or virtually all” or that is merely “speculation” is demonstrably baseless.¹¹⁸

Read charitably, Takeda’s argument appears to insist that, to be admissible, an expert assessment of antitrust impact must be articulated numerically (*e.g.*, a firm percentage of class members that were uninjured), rather than categorically (*e.g.*, “all or virtually all” were injured). But Takeda provides no basis in *Daubert* caselaw for such a requirement, because there is none. On the

¹¹² *Id.* ¶ 83.

¹¹³ *Id.* ¶¶ 88-90. *See Ranbaxy*, 338 F.R.D. at 306 (crediting expert’s opinion that “*meaningful generic competition* would likely cause all TPPs to purchase generics”) (emphasis added).

¹¹⁴ Kovach Rep., Doc No. 397-1, ¶ 90.

¹¹⁵ Kovach Rbl., Doc No. 528-1, ¶¶ 21-57, 65-80.

¹¹⁶ *Id.* ¶¶ 58-62.

¹¹⁷ *Id.* ¶ 62.

¹¹⁸ *See Kovach Daubert*, Doc No. 546 at 19.

contrary, courts overseeing TPP class actions regularly admit these categorical conclusions based on calculation of the probability that *any one* TPP would be uninjured in the but-for world as opposed to a percentage of the overall class.¹¹⁹ In *EpiPen*, plaintiffs’ class certification expert calculated that “the likelihood that a third-party payor who covered as few as five prescriptions sustained injury from generic delay is 99.999% or better.”¹²⁰ The court rejected defendants’ *Daubert* argument that a probability analysis “is not capable of measuring classwide injury” absent “a showing of actual injury to all or substantially all class members,” and ultimately admitted the expert opinion and certified the EPP class.¹²¹ Similarly, in the *Actos* fraudulent marketing litigation against Takeda, plaintiffs’ expert calculated that “any TPP that paid for at least five Actos prescriptions has, statistically, a 98.5% chance of suffering an injury.”¹²² There, too, the court recognized as reliable the conclusion that “the number of uninjured TPPs appears to be *de minimis*” and certified the class.¹²³

CONCLUSION

Takeda’s Motion to Exclude the Opinions and Testimony of Plaintiffs’ Expert Martin Kovach should be denied in its entirety.

¹¹⁹ During Dr. Kovach’s deposition, counsel for Takeda disregarded that Dr. Kovach did not formulate his ultimate conclusion in terms of a specific percentage of class members that were uninjured. Kovach Dep. Tr., Doc No. 547-1 at 157:11-12. Counsel instead relentlessly pushed Dr. Kovach to estimate a percentage on the spot, *id.* at 149:24-157:4, and Dr. Kovach appropriately rebuffed the demand “to give an expert opinion on something that I haven’t analyzed.” *Id.* at 152:11-12.

¹²⁰ *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. & Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, 2020 WL 1180550, at *32 (D. Kan. Mar. 10, 2020).

¹²¹ 2020 WL 1180550, at *20, 34-36.

¹²² *Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd.*, 674 F. Supp. 3d 799, 824 (C.D. Cal. 2023).

¹²³ *Id.* at 825.

Dated: April 30, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, William Fidurko, hereby certify that this document was electronically filed with the Clerk of the Court for the District of Massachusetts by using the CM/ECF System, which will send notification of such filing to all registered CM/ECF users. Counsel of record will also receive copies via electronic mail.

Dated: April 30, 2025

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